REMARKS

Claims 10-13 were previously pending in this application. Claims 10-12 have been amended, claim 13 has been cancelled without prejudice to or disclaimer of the underlying subject matter, and new claims 14-19 have been added. Support for the new and amended claims can be found throughout the specification, for example, at page 53, lines 16-23, at page 55 lines 9-23, and at page 60, line 19 through page 61, line 22, in the sequence listing, and in the claims as originally filed. No new matter enters by way of these amendments.

I. Election/Restrictions

The Examiner has required that Applicants elect a single nucleic acid sequences for further examination. Applicants respectfully traverse the restriction requirement, and provisionally elect SEQ ID NO: 1 for further prosecution.

Applicants submit that election of a single nucleotide sequence is improper and Applicants believe no serious burden would result by the search and examination of at least ten nucleotide sequences. The election of a single nucleic acid sequence contravenes the United States Patent and Trademark Office policy as set forth in the Manual of Patent Examining Procedure stating that "to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided ... to permit a reasonable number of such nucleotide sequences to be claimed in a single application." (MPEP, 8th ed., August 2001, Section 803.04). The MPEP further provides that "[i]t has been determined that normally ten sequences constitute a reasonable number for examination purposes." (emphasis added) *Id.* While the Examiner requires that a single nucleotide sequence be selected, no reason has been provided for this deviation from articulated Patent Office policy.

Based upon the foregoing, Applicants submit that the election requirement is improper and therefore must be withdrawn. To facilitate prosecution, however, Applicants provisionally elect, with traverse, SEQ ID NO: 1.

II. Claim Rejections – 35 U.S.C. § 101

Claims 10-12 have been rejected under 35 U.S.C. § 101 because the claimed invention allegedly lacks patentability due to its not being supported by either specific and/or substantial utility or a well established utility. Office Action page 5. Applicants respectfully disagree.

The Examiner acknowledges that the specification describes multiple utilities for the present invention, including "markers, the isolation of polypeptides, hybridization probes, primers, the isolation of full-length cDNAs or genes which would be used to make protein...for mapping and numerous other generic genetic engineering usages." Office Action page 5. Moreover, other utilities are set forth in the specification. *See* page 73 *et seq.* under "Uses of the Agents of the Invention." However, the Examiner contends that none of these utilities constitute a "substantial" or "specific" utility. Applicants respectfully disagree with this assertion.

It is well established that "when a properly claimed invention meets at least one stated objective, utility under 35 U.S.C. § 101 is clearly shown." *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 298 (Fed. Cir. 1983). The present specification describes many objectives that are met by the present invention. In addition to the utilities described by the Examiner (quoted above), the claimed nucleic acid molecules are useful for obtaining protein molecules, determining the presence and/or identity of polymorphisms, measuring the levels of mRNA in a sample, determining the location of a corresponding DNA sequence on a physical or genetic map, probing for other molecules, generating primers, obtaining other nucleic acid molecules from the same species, obtaining related protein coding sequences, obtaining promoters and other flanking genetic elements, screening cDNA genomic libraries, obtaining nucleic acid homologs, detecting and characterizing gene expression, etc. *See, e.g.*, specification at page 73 *et seq.* under "Uses of the Agents of the Invention."

Many of these uses are directly analogous to a microscope. An important utility of a microscope resides in its use to identify and characterize the structure of biological tissues in a sample, cell, or organism. Significantly, the utility of the microscope under 35 U.S.C. § 101 is not compromised by its use as a tool in this manner. Many of the presently disclosed utilities are directly analogous to the utilities of a microscope, *i.e.*, the claimed nucleic acid molecules may be used to identify and characterize other nucleic acid molecules within a sample, cell or

organism. Such utility is indistinguishable from the legally sufficient utility of a microscope. Thus, the presently disclosed sequences possess the requisite utility under 35 U.S.C. § 101.

In the Office Action, the Examiner provides no evidence challenging the disclosed utilities for the presently claimed nucleic acid molecules. Rather the Examiner attempts to undermine the existing utilities by stating that they are "non-specific uses that are applicable to nucleic acid(s) and/or proteins in general and not particular or specific to the nucleic acids being claimed." Office Action page 5. In short, the Examiner suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose. This position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stifung v. Renishaw PLC*, 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result...").

For example, such an argument implies that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.,* hitting golf balls. Such a result is not only untenable, but requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty*, 447 U.S. 303, 308, 306 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.,* 289 U.S. 178, 199, 17 U.S.P.Q. 154, 163 (1933). Thus, it must be the case that a utility, generic to a broad class of molecules, does not compromise the specific utility of an individual member of that class.

As noted above, the claimed nucleic acid molecules have many utilities. Some of these utilities may be common to a broader class of molecules. For instance, nucleic acid sequences may generally be used to identify and locate related sequences. However, when used in this manner, the result is not generic. Rather, the claimed nucleic acid molecules will identify a ***unique*** subset of related sequences. This subset of related sequences is specific to the claimed sequences and cannot be identified by any generic nucleic acid molecule. For example, a random nucleic acid molecule would not provide this specific utility. Referring again to the golf club analogy, the club is still generically hitting a golf ball, but is uniquely designed to hit a ball in a manner that is distinct from other clubs. Once again, Applicants assert that the claimed nucleic

acid sequences exhibit the requisite utility under 35 U.S.C. § 101.

III. Claim Rejections – 35 U.S.C. § 112, First Paragraph, Enablement

The Examiner has rejected claims 10-12 as not being enabled by the specification, because the claimed invention allegedly lacks utility. Office Action page 6. Applicants respectfully disagree.

Applicants assert that the rejection is erroneous and has been overcome by the foregoing arguments regarding utility. Thus, the enablement rejection under 35 U.S.C. § 112, first paragraph is improper. Reconsideration and withdrawal are respectfully requested.

IV. Claim Rejections – 35 U.S.C. § 112, First Paragraph, Written Description

The Examiner has rejected claims 10-12 under 35 U.S.C. § 112, first paragraph, for allegedly lacking an adequate written description. Office Action at page 7. Applicants respectfully disagree.

Although the Examiner acknowledges that the specification discloses SEQ ID NO: 1, claims 10-12 allegedly fail to meet the written description requirement because the "specification provides insufficient written description to support the genus encompassed by the claim." Office Action page 7. Applicants respectfully disagree with this contention.

An adequate written description of a genus of nucleic acids may be achieved by either "a recitation of a representative number of [nucleic acid molecules], defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus." *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69 (Fed. Cir. 1997). The feature relied upon to describe the claimed genus must be capable of distinguishing members of the claimed genus from non-members. *Id.*

The purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). In accordance with this purpose, Applicants need not "describe," in the sense of

Section 112, all things that are encompassed by the claims. To contend otherwise would contradict established jurisprudence, which teaches that a patent may be infringed by technology developed after a patent issues. *United States Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1251, 9 U.S.P.Q.2d 1461, 1464 (Fed. Cir. 1989). A related, and equally well-established principle of patent law is that claims "may be broader than the specific embodiment disclosed in a specification." *Ralston Purina Co. v. Far-mor-Co*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985), *quoting In re Rasmussen*, 650 F.2d 1212, 1215, 211 U.S.P.Q. 323, 326 (C.C.P.A. 1981). Thus, in order for Applicants to describe each and every molecule encompassed by the claims, it is not required that every aspect of those nucleic acid molecules (*e.g.*, an open reading frame) be disclosed. *In re Alton,* 76 F.3d 1168, 1175 (Fed. Cir. 1996) (if a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing even if every nuance of the claims is not explicitly described in the specification).

The Examiner further contends that "the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides." Office Action page 7. According to the Examiner, proper written description support for a claim directed to a nucleic acid sequence requires nothing less than the actual disclosure of every sequence encompassed by that claim. In support of this proposition, the Examiner relies on *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997). Applicants respectfully disagree. In *Eli Lilly* the court found that claims to a vertebrate cDNA coding insulin were inadequately described. However, the present case is clearly different. Specifically, the present claims "distinguish the claimed genus from others" and define "structural features commonly possessed by members of the genus that distinguishes them from others," unlike the claims at issue in *Eli Lilly*. *Id.* at 1568-69 ("a cDNA is not defined or described by the mere name 'cDNA'...but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the DNA.").

In particular, Applicants have provided a detailed chemical structure, *i.e.*, the nucleic acid sequence of SEQ ID NO: 1. Moreover, nucleic acid molecules falling within the scope of the claims are readily identifiable – they comprise a nucleic acid molecule having the nucleic acid

sequence of SEQ ID NO: 1 or the complete complement thereof, or that hybridizes to the nucleic acid molecule under the recited conditions. The fact that the nucleic acid molecules may comprise additional sequences or variations is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed through the present specification. Thus, there is no deficiency in the written description support for claims 10-12. Therefore, claims 10-12 satisfy the written description requirement of 35 U.S.C. § 112, first paragraph. Reconsideration and withdrawal of this rejection are respectfully requested.

V. Claim Rejections – 35 U.S.C. § 112, Second Paragraph

Claims 11 and 12 were rejected under 35 U.S.C. § 112, Second Paragraph, for allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Office Action page 9. The Examiner contents that "[c]laims 11 and 12 are vague and indefinite as to what is meant therein by the limitation 'the complement.'" Office Action page 9.

Applicants respectfully disagree with the Examiner's contention, however, to facilitate prosecution, Applicants have amended claims 11-12. Withdrawal of this rejection is respectfully requested.

VI. Claim Rejections – 35 U.S.C. § 102

Claims 11-12 have been rejected under 35 U.S.C. § 102, as allegidly being anticipated by GenBank Accession Number D30807 (8 March 1995, hereinafter "D30807"). Office Action page 9. Applicants respectfully disagree. For a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention must be identically shown in a single reference. *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 677, 7 U.S.P.Q. 2d 1315, 1317 (Fed. Cir. 1988). *See also Kalman v. Kimberly Clark Corp.*, 713 F.2d 760, 771 (Fed. Cir. 1983), *cert. denied*, 465 U.S. 1026 (1984). D30807 does not teach every element of the claimed invention.

The Examiner alleges that "D30807 is identical from nucleic acids 1-267 to SEQ ID NO: 1 nucleic acids 54-320 and would therefore hybridize under the claimed conditions to SEQ ID NO: 1 set forth in the instant claims." Office Action at page 10. However, no evidence, extrinsic

or otherwise, has been presented by the Examiner in support of the proposition that D30807 would necessarily hybridize to SEQ ID NO: 1. Instead of providing evidence, the Examiner appears to shift the burden of proof to Applicants to provide evidence that the nucleic acids are not identical. This is not the law.

Applicants respectfully disagree that the region of homology cited by the Examiner is sufficient to permit hybridization over the entire SEQ ID NO: 1 (320 base pairs having 83.4% homology) under the claimed conditions. Applicants contend the rejection under 35 U.S.C. § 102(b) is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is now in condition for allowance, and notice of such is respectfully requested.

The Examiner is encouraged to contact the undersigned should any additional information be necessary for allowance.

Respectfully submitted,

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Date: December 9, 2003

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